

Claims:

Claim 1 (Withdrawn): A method for treating a cancer in a patient in need thereof comprising administering to said patient, concurrently or sequentially, a therapeutically effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor and at least one signal transduction inhibitor (STI).

Claim 2 (Withdrawn): The method of claim 1, wherein said at least one STI is selected from the group consisting of bcr/abl kinase inhibitors, epidermal growth factor (EGF) receptor inhibitors, her-2/neu receptor inhibitors, farnesyl transferase inhibitors (FTIs), inhibitors of Akt family kinases or the Akt pathway, and cell cycle kinase inhibitors.

Claim 3 (Withdrawn): The method of claim 2, wherein said at least one STI is selected from the group consisting of STI 571, SSI-774, C225, ABX-EGF, trastuzumab, L-744,832, rapamycin, LY294002, flavopiridal, and UNC-01.

Claim 4 (Withdrawn): The method of claim 3, wherein said at least one STI is L-744,832.

Claim 5 (Withdrawn): The method of claim 1, wherein said at least one IDO inhibitor is selected from the group consisting of 1-methyl-DL-tryptophan (1MT), β -(3-benzofuranyl)-DL-alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-tryptophan, indole 3-carbinol, 3,3'-diindolylmethane, brassinin, 3,3'-diindolylmethane, indole-3-carbinol, 5-methyl-brassinin, epigallocatechin gallate, 5-Br-4-Cl-indoxyl 1,3-diacetate, 9-vinylcarbazole, acemetacin, 5-bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-DL-trp, propenyl-TH-DL-trp, methyl-TH-DL-trp, brassilexin, 3-amino-2-naphthoic acid, β -carboline, 3-butyl- β -carboline, 6-fluoro-3-carbomethoxy- β -carboline, 6-isothiocyanate-3-carbomethoxy- β -

carboline, 3-propoxy- β -carboline, 3-carboxy- β -carboline, 3-carbopropoxy- β -carboline, and 3-carbo-tert-butoxy- β -carboline.

Claim 6 (Withdrawn): The method of claim 5, wherein said at least one IDO inhibitor is 1-methyl-tryptophan (1MT).

Claim 7 (Withdrawn): The method of claim 1, wherein said at least one IDO inhibitor and said at least one STI are administered concurrently.

Claim 8 (Withdrawn): The method of claim 1, wherein said at least one IDO inhibitor and said at least one STI are administered sequentially.

Claim 9 (Withdrawn): The method of claim 8, wherein said at least one IDO inhibitor is administered before said at least one STI.

Claim 10 (Withdrawn): The method of claim 8, wherein said at least one STI is administered before said at least one IDO inhibitor.

Claim 11 (Withdrawn): The method of claim 1, wherein said cancer is selected from the group consisting of cancers of the prostate, colorectum, pancreas, cervix, stomach, endometrium, brain, liver, bladder, ovary, testis, head, neck, skin (including melanoma and basal carcinoma), mesothelial lining, white blood cell (including lymphoma and leukemia) esophagus, breast, muscle, connective tissue, lung (including small-cell lung carcinoma and non-small-cell carcinoma), adrenal gland, thyroid, kidney, or bone; glioblastoma, mesothelioma, renal cell carcinoma, gastric carcinoma, sarcoma, choriocarcinoma, cutaneous basocellular carcinoma, and testicular seminoma.

Claim 12 (Withdrawn): A pharmaceutical composition for the treatment of a cancer comprising an effective amount of at

least one indoleamine 2,3-dioxygenase (IDO) inhibitor and at least one signal transduction inhibitor (STI) in a pharmaceutically acceptable carrier medium.

Claim 13 (Withdrawn): The pharmaceutical composition of claim 12, wherein said at least one STI is selected from the group consisting of bcr/abl kinase inhibitors, epidermal growth factor (EGF) receptor inhibitors, her-2/neu receptor inhibitors, farnesyl transferase inhibitors (FTIs), inhibitors of Akt family kinases or the Akt pathway, and cell cycle kinase inhibitors.

Claim 14 (Withdrawn): The pharmaceutical composition of claim 13, wherein said at least one STI is selected from the group consisting of STI 571, SSI-774, C225, ABX-EGF, trastuzumab, L-744,832, rapamycin, LY294002, flavopiridal, and UNC-01.

Claim 15 (Withdrawn): The pharmaceutical composition of claim 13, wherein said at least one STI is L-744,832.

Claim 16 (Withdrawn): The pharmaceutical composition of claim 12, wherein said at least one inhibitor of IDO is selected from the group consisting of 1-methyl-DL-tryptophan (1MT), β -(3-benzofuranyl)-DL-alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-tryptophan, indole 3-carbinol, 3,3'-diindolylmethane, brassinin, 3,3'-diindolylmethane, indole-3-carbinol, 5-methyl-brassinin, epigallocatechin gallate, 5-Br-4-Cl-indoxyl 1,3-diacetate, 9-vinylcarbazole, acemetacin, 5-bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-DL-trp, propenyl-TH-DL-trp, methyl-TH-DL-trp, brassilexin, 3-amino-2-naphthoic acid, β -carboline, 3-butyl- β -carboline, 6-fluoro-3-carbomethoxy- β -carboline, 6-isothiocyanate-3-carbomethoxy- β -carboline, 3-propoxy- β -carboline, 3-carboxy- β -carboline, 3-carbopropoxy- β -carboline, and 3-carbo-tert-butoxy- β -carboline.

Claim 17 (Withdrawn): The pharmaceutical composition of claim 12, wherein said at least one IDO inhibitor is 1-methyl-tryptophan (1MT).

Claim 18 (Withdrawn): A method for treating a cancer in a patient in need thereof comprising administering to said patient, concurrently or sequentially, a therapeutically effective amount of at least one immunomodulator, other than IDO inhibitor, and an effective amount of at least one cytotoxic chemotherapeutic agent or at least one STI.

Claim 19 (Withdrawn): The method of claim 18, wherein said at least one immunomodulator is selected from the group consisting of CD40L, B7, B7RP1, ant-CD40, anti-CD38, anti-ICOS, 4-IBB ligand, dendritic cell cancer vaccine, IL2, IL12, IL1, IL18, ELC/CCL19, SLC/CCL21; MCP-1, IL-4, IL-18, TNF, IL-15, MDC, IFNa/b, M-CSF, IL-3, GM-CSF, IL-13, anti-IL-10, bacterial lipopolysaccharide (LPS), and poly CpG DNA.

Claim 20 (Withdrawn): The method of claim 18, wherein said at least one cytotoxic chemotherapeutic agent is selected from the group consisting of paclitaxel (Taxol®), cisplatin, docetaxol, carboplatin, vincristine, vinblastine, methotrexate, cyclophosphamide, CPT-11, 5-fluorouracil (5-FU), gemcitabine, estramustine, carmustine, adriamycin (doxorubicin), etoposide, arsenic trioxide, irinotecan, and epothilone derivatives.

Claim 21 (Withdrawn): The method of claim 18, wherein said at least one STI is selected from the group consisting of STI 571, SSI-774, C225, ABX-EGF, trastuzumab, L-744,832, rapamycin, LY294002, flavopiridal, and UNC-01.

Claim 22 (Withdrawn): A method for treating a chronic viral infection in a patient in need thereof comprising administering to said patient, concurrently or sequentially, a

therapeutically effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor and at least one chemotherapeutic agent.

Claim 23 (Withdrawn): The method of claim 22, wherein said at least one IDO inhibitor is selected from the group consisting of 1-methyl-DL-tryptophan (1MT), β -(3-benzofuranyl)-DL-alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-tryptophan, indole 3-carbinol, 3,3'-diindolylmethane, brassinin, 3,3'-diindolylmethane, indole-3-carbinol, 5-methyl-brassinin, epigallocatechin gallate, 5-Br-4-Cl-indoxyl 1,3-diacetate, 9-vinylcarbazole, acemetacin, 5-bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-DL-trp, propenyl-TH-DL-trp, methyl-TH-DL-trp, brassilexin, 3-amino-2-naphthoic acid, β -carboline, 3-butyl- β -carboline, 6-fluoro-3-carbomethoxy- β -carboline, 6-isothiocyanate-3-carbomethoxy-p-carboline, and 3-propoxy- β -carboline, 3-carboxy- β -carboline, 3-carbopropoxy- β -carboline, and 3-carbo-tert-butoxy- β -carboline.

Claim 24 (Withdrawn): The method of claim 22, wherein said at least one IDO inhibitor is 1-methyl-tryptophan (1MT).

Claim 25 (Withdrawn): The method of claim 22, wherein said at least one chemotherapeutic agent is selected from the group consisting of paclitaxel (Taxol®), cisplatin, docetaxol, carboplatin, vincristine, vinblastine, methotrexate, cyclophosphamide, CPT-11, 5-fluorouracil (5-FU), gemcitabine, estramustine, carmustine, adriamycin (doxorubicin), etoposide, arsenic trioxide, irinotecan, and epothilone derivatives.

Claim 26 (Withdrawn): The method of claim 22, wherein said at least one IDO inhibitor and said at least one chemotherapeutic agent are administered concurrently.

Claim 27 (Withdrawn): The method of claim 22, wherein said at least one IDO inhibitor and said at least one chemotherapeutic agent are administered sequentially.

Claim 28 (Withdrawn): The method of claim 27, wherein said at least one IDO inhibitor is administered before said at least one chemotherapeutic agent.

Claim 29 (Withdrawn): The method of claim 27, wherein said at least one chemotherapeutic agent is administered before said at least one IDO inhibitor.

Claim 30 (Withdrawn): The method of claim 22, wherein said chronic viral infection is selected from the group consisting of: hepatitis C virus (HCV), human papilloma virus (HPV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), varicella zoster virus, coxsackie virus, human immunodeficiency virus (HIV).

Claim 31 (Withdrawn): A pharmaceutical composition for the treatment of a chronic viral infection comprising an effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor, at least one chemotherapeutic agent, and a pharmaceutically acceptable carrier medium.

Claim 32 (Withdrawn): The pharmaceutical composition of claim 31, wherein said at least one inhibitor of IDO is selected from the group consisting of 1-methyl-DL-tryptophan (1MT), β -(3-benzofuranyl)-DL-alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-tryptophan, indole 3-carbinol, 3,3'-diindolylmethane, brassinin, 3,3'-diindolylmethane, indole-3-carbinol, 5-methyl-brassinin, epigallocatechin gallate, 5-Br-4-Cl-indoxyl 1,3-diacetate, 9-vinylcarbazole, acemetacin, 5-bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-DL-trp, propenyl-TH-DL-trp, methyl-TH-DL-trp, brassilexin, 3-amino-2-naphthoic acid, β -carboline, 3-butyl- β -carboline, 6-

fluoro-3-carbomethoxy- β -carboline, 6-isothiocyanate-3-carbomethoxy- β -carboline, 3-propoxy- β -carboline, 3-carboxy- β -carboline, 3-carbopropoxy- β -carboline, and 3-carbo-tert-butoxy- β -carboline.

Claim 33 (Withdrawn): The pharmaceutical composition of claim 32, wherein said at least one IDO inhibitor is 1-methyl-tryptophan (1MT).

Claim 34 (Withdrawn): The pharmaceutical composition of claim 31, wherein said at least one chemotherapeutic agent is selected from the group consisting of paclitaxel (Taxol®), cisplatin, docetaxol, carboplatin, vincristine, vinblastine, methotrexate, cyclophosphamide, CPT-11, 5-fluorouracil (5-FU), gemcitabine, estramustine, carmustine, adriamycin (doxorubicin), etoposide, arsenic trioxide, irinotecan, and epothilone derivatives.

Claim 35 (Withdrawn): A method for treating a cancer in a patient in need thereof comprising administering to said patient a therapeutically effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor, wherein said IDO inhibitor selected from the group consisting of: phenyl-TH-DL-trp (3-(N-phenyl-thiohydantoin)-indole), propenyl-TH-DL-trp (3-(N-allyl-thiohydantoin)-indole), and methyl-TH-DL-trp (3-(N-methyl-thiohydantoin)-indole).

Claim 36 (Withdrawn): The method of claim 35, wherein said cancer is selected from the group consisting of cancers of the prostate, colorectum, pancreas, cervix, stomach, endometrium, brain, liver, bladder, ovary, testis, head, neck, skin (including melanoma and basal carcinoma), mesothelial lining, white blood cell (including lymphoma and leukemia) esophagus, breast, muscle, connective tissue, lung (including small-cell lung carcinoma and non-small-cell carcinoma), adrenal gland, thyroid, kidney, or bone; glioblastoma, mesothelioma, renal

cell carcinoma, gastric carcinoma, sarcoma, choriocarcinoma, cutaneous basocellular carcinoma, and testicular seminoma.

Claim 37 (Withdrawn): A pharmaceutical composition for the treatment of a cancer comprising an effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor, wherein said IDO inhibitor selected from the group consisting of: phenyl-TH-DL-trp (3-(N-phenyl-thiohydantoin)-indole), propenyl-TH-DL-trp (3-(N-allyl-thiohydantoin)-indole), and methyl-TH-DL-trp (3-(N-methyl-thiohydantoin)-indole); and a pharmaceutically acceptable carrier.

Claim 38 (Original): A method for treating a cancer in a patient in need thereof comprising administering to said patient, concurrently or sequentially, a therapeutically effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor and at least one chemotherapeutic agent.

Claim 39 (Original): The method of claim 38, wherein said at least one chemotherapeutic agent is selected from the group consisting of paclitaxel (Taxol®), cisplatin, docetaxol, carboplatin, vincristine, vinblastine, methotrexate, cyclophosphamide, CPT-11, 5-fluorouracil (5-FU), gemcitabine, estramustine, carmustine, adriamycin (doxorubicin), etoposide, arsenic trioxide, irinotecan, and epothilone derivatives.

Claim 40 (Withdrawn): The method of claim 39, wherein said at least one chemotherapeutic agent is paclitaxel.

Claim 41 (Previously Presented): The method of claim 38, wherein said at least one IDO inhibitor is selected from the group consisting of 1-methyl-DL-tryptophan (1MT), β -(3-benzofuranyl)-DL-alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-tryptophan, brassinin, 5-methyl-brassinin, 5-Br-4-Cl-indoxyl 1,3-diacetate, 9-vinylcarbazole, acemetacin, 5-bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-DL-

trp, propenyl-TH-DL-trp, methyl-TH-DL-trp, brassilexin, 3-amino-2-naphthoic acid, β -carboline, 3-butyl- β -carboline, 6-fluoro-3-carbomethoxy- β -carboline, 6-isothiocyanate-3-carbomethoxy- β -carboline, 3-propoxy- β -carboline, 3-carboxy- β -carboline, 3-carbopropoxy- β -carboline, and 3-carbo-tert-butoxy- β -carboline.

Claim 42 (Original): The method of claim 41, wherein said at least one IDO inhibitor is 1-methyl-tryptophan (1MT).

Claim 43 (Original): The method of claim 38, wherein said at least one IDO inhibitor and said at least one chemotherapeutic agent are administered concurrently.

Claim 44 (Original): The method of claim 38, wherein said at least one IDO inhibitor and said at least one chemotherapeutic agent are administered sequentially.

Claim 45 (Original): The method of claim 44, wherein said at least one IDO inhibitor is administered before said at least one chemotherapeutic agent.

Claim 46 (Original): The method of claim 44, wherein said at least one chemotherapeutic agent is administered before said at least one IDO inhibitor.

Claim 47 (Original): The method of claim 38, wherein said cancer is selected from the group consisting of cancers of the prostate, colorectum, pancreas, cervix, stomach, endometrium, brain, liver, bladder, ovary, testis, head, neck, skin (including melanoma and basal carcinoma), mesothelial lining, white blood cell (including lymphoma and leukemia) esophagus, breast, muscle, connective tissue, lung (including small-cell lung carcinoma and non-small-cell carcinoma), adrenal gland, thyroid, kidney, or bone; glioblastoma, mesothelioma, renal

cell carcinoma, gastric carcinoma, sarcoma, choriocarcinoma, cutaneous basocellular carcinoma, and testicular seminoma.

Claim 48 (Withdrawn): A pharmaceutical composition for the treatment of a cancer comprising an effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor and at least one chemotherapeutic agent in a pharmaceutically acceptable carrier medium.

Claim 49 (Withdrawn): The pharmaceutical composition of claim 48, wherein said at least one chemotherapeutic agent is selected from the group consisting of paclitaxel (Taxol®), cisplatin, docetaxol, carboplatin, vincristine, vinblastine, methotrexate, cyclophosphamide, CPT-11, 5-fluorouracil (5-FU), gemcitabine, estramustine, carmustine, adriamycin (doxorubicin), etoposide, arsenic trioxide, irinotecan, and epothilone derivatives.

Claim 50 (Withdrawn): The pharmaceutical composition of claim 49, wherein said at least one STI is paclitaxel.

Claim 51 (Withdrawn): The pharmaceutical composition of claim 48, wherein said at least one inhibitor of IDO is selected from the group consisting of 1-methyl-DL-tryptophan (1MT), β -(3-benzofuranyl)-DL-alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-tryptophan, indole 3-carbinol, 3,3'-diindolylmethane, brassinin, 3,3'-diindolylmethane, indole-3-carbinol, 5-methyl-brassinin, epigallocatechin gallate, 5-Br-4-Cl-indoxyl 1,3-diacetate, 9-vinylcarbazole, acemetacin, 5-bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-DL-trp, propenyl-TH-DL-trp, methyl-TH-DL-trp, brassilexin, 3-amino-2-naphthoic acid, β -carboline, 3-butyl- β -carboline, 6-fluoro-3-carbomethoxy- β -carboline, 6-isothiocyanate-3-carbomethoxy- β -carboline, 3-propoxy- β -carboline, 3-carboxy- β -carboline, 3-carbopropoxy- β -carboline, and 3-carbo-tert-butoxy- β -carboline.

Claim 52 (Withdrawn): The pharmaceutical composition of claim 48, wherein said at least one IDO inhibitor is 1-methyl-tryptophan (1MT).

Claim 53 (Previously Presented): The method of claim 41, wherein said IDO inhibitor is methyl-TH-DL-trp.

Claim 54 (Previously Presented): The method of claim 41, wherein said IDO inhibitor is 1-methyl-DL-tryptophan.

Claim 55 (Previously Presented): The method of claim 47, wherein said cancer is selected from the group consisting of melanoma, breast cancer, colorectal cancer, and lung cancer.

Claim 56 (Previously Presented): The method of claim 55, wherein said cancer is breast cancer.